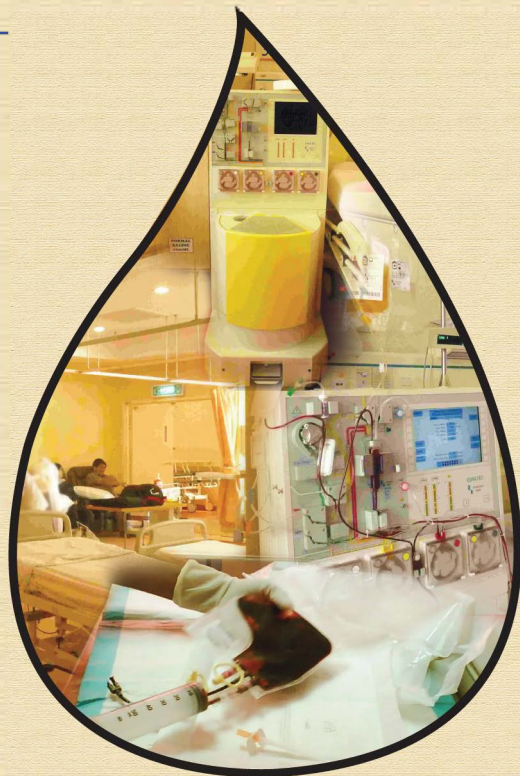


NATIONAL GUIDELINES FOR HAEMOPOIETIC STEM CELL THERAPY



The National Guidelines For Haemopoietic Stem Cell Therapy was prepared by
Obstetric & Gynaecological and Paediatric Services Unit of the Medical Services
Development Section, Medical Development Division, Ministry of Health Malaysia,
in collaboration with the Stem Cell Therapy Subcommittee

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CONTENTS

Foreword

Director General of Health Malaysia	6
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Articles

1.0	Introduction	11
2.0	General	12
3.0	Transplant Unit	13
	3.1 Clinical	13
	3.2 Laboratory	14
	3.3 Supportive Services	15
4.0	Personnel	16
5.0	Indications for Haemopoietic Stem Cell Transplantation	18
6.0	Patient Evaluation	19
7.0	Donor Evaluation and Management	20
8.0	Donor Consent	23
9.0	Cord Blood Unit (CBU)	24

10.0	Proficiency of The Transplant Physician/Team	25
10.1	Stem Cell Selection	25
10.2	Transplant Related/Transplant Specific Procedures	25
10.3	Infectious Complications	26
10.4	Regimen Related Toxicities	26
10.5	Post Transplant Issues	27
10.6	Palliative Care	27
11.0	Policies and Procedures	28
12.0	Protocols For Conditioning	28
13.0	Quality Management	29

Appendix

I	: Proposed Classification of Transplant Indications in Adult	33
II	: Proposed Classification of Transplant Indications in Children	39
III	: Reference	43

Editorial Board for National Guidelines For Haemopoietic Stem Cell Therapy (HSCT) in Malaysia	49
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Acknowledgement	55
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FOREWORD



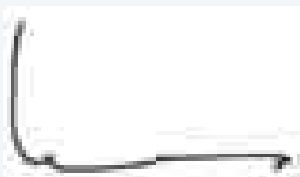
**DIRECTOR GENERAL
OF
HEALTH MALAYSIA**

Haemopoietic stem cell transplant is a cure for many haemopoietic malignancies and genetic diseases involving the lymphohaemopoietic system. It is cost-effective and many patients, both young and old, are able to return to full-time employment after the therapy. Stem cell transplant today is also safe because of the lesser toxicity from the reduced chemoradiation conditioning and better supportive care and treatment facilities.

This current edition of the National Guidelines for Haemopoietic Stem Cell Therapy stipulates the required standards for any clinical facility in Malaysia performing haemopoietic stem cell transplants. It outlines the proficiency of the personnel, the evaluation of both donors and patients as well as the quality management policy that needs to be put in place to ensure the safety of patient and donors. The working committee has also included the currently-accepted indications which will, of course, expand over time.

Haemopoietic stem cells are easily accessible from the bone marrow, peripheral blood and the umbilical cord blood. Although there has been a lot of interest regarding the potential use of embryonic cells, which have pluripotential capacity to differentiate into all cell types, in specific disease conditions, the working committee remains cautious in recommending such therapies at this time as the degree of development plasticity remains unclear. It is therefore recommended that indications which are experimental and promising e.g. for tissue repair and revascularization, shall be studied further in the context of clinical trials together with IRB review and approval.

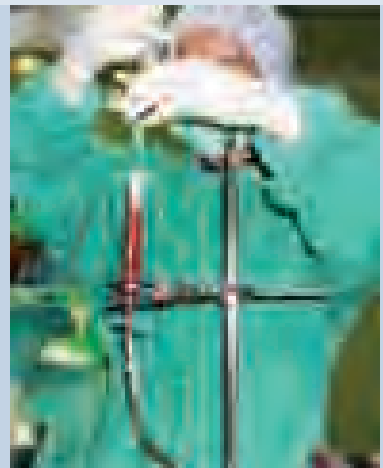
I would like to congratulate the Medical Development Division of the Ministry of Health and the working committee for putting together this comprehensive guideline. I urge all specialists performing stem cell transplants to adhere to the recommendations put forward in the guideline.



TAN SRI DATO' SERI DR. HJ. MOHD ISMAIL MERICAN

Director General of Health, Malaysia

Haemopoietic Stem Cell



1.0 INTRODUCTION

Stem cells are a population of undifferentiated cells characterized by 3 main properties – the ability to divide indefinitely, to self-renew and to generate a progeny of specialised cells. Stem cell sources include the fertilized egg, embryonic stem cells and adult somatic stem cells found in the blood and marrow, brain, neural and other tissues. Currently it is the haemopoietic stem cell transplants that are the most established form of therapy.

Haemopoietic stem cell transplants are performed to treat a variety of life threatening malignant and non-malignant disorders. With the continued advancement in the transplantation procedure, the development of new conditioning regimes – myeloablative and non-myeloablative as well as the use of new haemopoietic stem cell sources – peripheral blood and cord blood, the list of indications will continue to increase. It is a requirement that the harvesting, procurement and transplantation procedures are done in accredited centres with experienced personnel and good supportive facilities.

The purpose of this document is to establish National Standards for all centres in Malaysia performing haemopoietic stem cell transplantations.

2.0 GENERAL

- 2.1 A Clinical Haemopoietic Stem Cell Transplant Programme shall comprise a core team of personnel who are trained in the field of Haemopoietic Stem Cell Therapy (HSCT) and the management of haematological diseases. There shall be a Programme Head and a team of trained personnel, a transplantation ward and access to an accredited stem cell laboratory.
- 2.2 All policies, procedures and protocols, as well as quality management systems shall be established and documented.
- 2.3 All centres performing HSCT shall seek accreditation.
- 2.4 A minimum of 10 transplants shall be performed yearly to attain sufficient proficiency. To achieve accreditation as an allogeneic centre, a minimum of 10 allogeneic transplants shall be performed each year. Centres performing transplants for both paediatric and adult patients shall perform transplants on at least 5 adults and 5 paediatric patients each year. Centres performing autologous transplants only shall perform a minimum of 10 transplants each year. Centres performing both shall meet the requirements of an allogeneic transplant centre.

3.0 TRANSPLANT UNIT

The transplant unit shall have:

3.1 CLINICAL

- 3.1.1 A designated inpatient unit that minimizes airborne microbial contamination ideally HEPA filtration with positive pressure or laminar airflow for allogeneic transplants.
- 3.1.2 Autologous-HSCT patients and hospitalized HSCT patients can be nursed in isolation rooms.
- 3.1.3 A designated outpatient daycare unit.
- 3.1.4 Provisions shall be made for prompt evaluation and treatment of patients with complications on a 24-hours basis. This is usually in the daycare unit during office hours and in the transplant ward or haematology ward after hours.

3.2 LABORATORY

- 3.2.1 A stem cell laboratory that is accredited for stem cell harvest, enumeration, processing and cryopreservation shall be available within the vicinity. The stem cell laboratory shall conform to the National Standards of Stem Cell Procurement, Storage and Allocation.
- 3.2.2 Centres performing allogeneic haemopoietic stem cell transplants shall have access to a HLA-testing laboratory with the capability to carry out DNA-based HLA-typing. This HLA-laboratory shall seek local as well as international accreditation.
- 3.2.3 A good laboratory support with availability of microbiological tests, monitoring of drug levels, chimerism study and histopathology services is important. The pathologist shall have experience in the histological interpretation of graft - versus-host disease

3.3 SUPPORTIVE SERVICES

- 3.3.1 A transfusion service shall be available to provide irradiated blood products on a 24-hour basis.
- 3.3.2 A pharmacy shall be available to provide essential medications on a 24-hour basis.
- 3.3.3 A radiotherapy service shall be available within the vicinity.
- 3.3.4 Supportive services including specialists in the field of radiology, intensive care, neurology, nephrology, respiratory medicine, gastroenterology, cardiology and infectious disease shall be available for consultations.

4.0 PERSONNEL

- 4.1 The Head of Clinical Transplant Services shall be a clinician who has at least one year specific training in haemopoietic stem cell transplantation.
- 4.2 The adult stem cell transplant centre shall have at least one physician certified in Internal Medicine and accredited in Haematology or Medical Oncology or Immunology.
- 4.3 Centres performing paediatric transplants shall have at least a one physician certified in Paediatrics and accredited in Haematology/ Oncology or Immunology.

All physicians shall be licensed medical practitioners registered with the Malaysian Medical Council with a recognized post-graduate/ specialist certification e.g Masters in Internal Medicine or Paediatrics, MRCP or in Internal Medicine or Paediatrics and accredited in one of the following medical subspecialties : Haematology, Haematology/Oncology , Medical Oncology or Immunology.

- 4.4 The transplant nurses shall be formally trained and experienced in the management of HSCT patients. Training shall include haematology patient care, administration of high-dose chemotherapy, growth factor and immunosuppressive medications, management and handling of central venous access, management of infectious complications associated with immunocompromised host, administration of blood products and some degree of intensive care. A minimum nurse:patient ratio of 1:2 is recommended.
- 4.5 Other supportive staff members shall include a transplant coordinator, pharmacy staff, dietary staff, social worker and physiotherapy staff and a data manager.

5.0 INDICATIONS FOR HAEMOPOIETIC STEM CELL TRANSPLANTATION

- 5.1 HSCT is currently performed for patients with malignant and non-malignant haematological conditions, solid organ tumours, inherited metabolic and primary immunodeficiency diseases. The list of standard indications is not exhaustive and will continue to expand.
- * Refer to appendix for proposed classification of transplant indications
- 5.2 Indications which are experimental e.g. tissue repair, angiogenesis and revascularization shall be studied as clinical trials until more evidence is obtained. Ethics review and approval shall be obtained from the relevant local institutions. This shall conform to the National Guidelines for Stem Cell Research and Therapy
- 5.3 Reduced-intensity transplants are recommended for high risk candidates who are deemed not suitable for conventional transplants e.g. elderly patients and those with comorbidities.

6.0 PATIENT EVALUATION

- 6.1 The centre shall be well-versed in the selection of appropriate patients and selection of preparative regimen.
- 6.2 Assessment of patient eligibility shall include medical fitness, medical history, physical examination and psychosocial evaluation.
- 6.3 Signed informed consent shall be obtained from the patient/legal guardian after a thorough discussion of the HSCT procedure and its risks.
- 6.4 Patients who have medical co morbidities shall have detailed counseling and documentation of the rationale for transplant.
- 6.5 If the patient's name is to be added to a HSCT registry, informed consent shall be obtained.

7.0 DONOR EVALUATION AND MANAGEMENT

- 7.1 The safety of the donor shall be maintained.
- 7.2 Donor medical history, physical examination, psychosocial evaluation and laboratory test results shall be performed and suitability documented before initiation of the recipient's preparative regimen. This includes history of vaccination and blood transfusion. Any abnormal findings shall be informed to the prospective donor with proper documentation and recommendations made for follow-up care.
- 7.3 The use of a donor not meeting the collection facility's documented donor acceptance criteria shall require documentation of the rationale for his/her selection by the transplant physician and the informed consent of the donor and the recipient (or their parents or respective legal guardians).
- 7.4 Pregnancy tests for donors of child-bearing potential shall be performed.

- 7.5 Laboratory tests required for donor selection shall be done by an accredited laboratory and include at least the following:
- (i) HLA-A, B, DR typing and other appropriate compatibility tests as indicated
 - (ii) ABO group and Rh type
 - (iii) Infectious disease screening including: HIV-1, HIV-2, HBV, HCV, CMV, toxoplasmosis and syphilis and, depending on the intended use of products, tests may be carried out for the following infectious diseases: EBV, HAV, VZV and HSV
- 7.6 Donor screening shall include questions to identify persons at high risk of blood borne virus infections.
- 7.7 Donor's fitness for marrow collection shall be documented.
- 7.8 In the case of more than one marrow collection from the same donor, the tests listed in 7.5(iii) shall be repeated prior to each collection if performed more than 30 days from the first collection.
- 7.9 PBSC donors shall be evaluated for the risk of apheresis donation with regards to central venous access and the use of growth factors as mobilization therapy.

- 7.10 A full blood count, including platelet count shall be performed within 72 hours prior to the first PBSC collection and within 24 hours before each subsequent apheresis.
- 7.11 In the case of multiple PBSC collections from the same donor, the tests in 7.5(iii) as appropriate shall be performed within 30 days prior to each collection.
- 7.12 In accordance to the National Organ, Tissue and Cell Transplantation Policy, donors shall not be offered any compensation or any form of reward.
- 7.13 Donors shall be followed-up with regards to their well-being according to the institution's practice.

8.0 DONOR CONSENT

- 8.1 Informed consent from the donor shall be obtained.
- 8.2 The donor shall be informed about the significant risks and benefits of the procedure, tests performed to protect the health of the donor and recipient, and the rights of the donor to review the results of their tests.
- 8.3 The donor shall be given the opportunity to ask questions and the right to refuse to donate.
- 8.4 In the case of a donor below the age of consent, informed consent shall be obtained from the donor's parents or legal guardian in accordance with the relevant law and documented.
- 8.5 If the donor's name is to be added to a HSC donor registry, informed consent shall be obtained and documented before the donor's name is added to a HSC donor registry.

9.0 CORD BLOOD UNIT (CBU)

- 9.1 Procurement of CBU shall be made from accredited Cord Blood Banks.
- 9.2 Adequate infectious screening shall be performed on both mothers and CBUs.
- 9.3 Selection of CBU shall take account of degree of HLA match, nucleated cell dose or CD34+ cell dose and viability assay.

10.0 PROFICIENCY OF THE TRANSPLANT PHYSICIAN/TEAM

The transplant team shall be proficient in the following procedures.

10.1 STEM CELL SELECTION

- i. Identification and selection of haemopoietic stem cell source, including use of donor registries.
- ii. Knowledge in methodology and implications of HLA-typing.

10.2 TRANSPLANT RELATED/TRANSPLANT SPECIFIC PROCEDURES

- i. Haemopoietic stem cell product thawing and infusion.
- ii. Handling of central venous access such as Hickman's catheter, mainly in situations of blocked lumen or indications for catheter removal.
- iii. Bone marrow harvest and apheresis procedures.
- iv. Administration of preparative regimen and growth factors.
- v. Management of patients receiving ABO incompatible haemopoietic stem cell products.
- vi. Diagnosis of haemopoietic stem cell engraftment failure.

10.3 INFECTIOUS COMPLICATIONS

- i. Management of neutropaenic fever.
- ii. Diagnosis and management of fungal infections.
- iii. Diagnosis and management of CMV infections and other viral infections in the post-transplant setting
- iv. Diagnosis and management of other opportunistic infections

10.4 REGIMEN RELATED TOXICITIES

- i. Management of regimen related organ toxicities.
- ii. Diagnosis and management of veno-occlusive disease of the liver.
- iii. Management of thrombocytopenia and bleeding.
- iv. Management of thrombotic thrombocytopenic purpura.
- v. Management of haemorrhagic cystitis
- vi. Management of mucositis, pain, nausea and vomiting

10.5 POST TRANSPLANT ISSUES

- i. Diagnosis and management of acute and chronic graft versus host disease (GVHD).
- ii. Evaluation of chimerism and management of engraftment failure.
- iii. Use of immunosuppressive therapy.
- iv. Monitoring of minimal residual disease, indications for donor lymphocytes and management of disease relapse.
- v. Diagnosis and management of post-transplant immunodeficiency and reimmunisation post-HSCT.
- vi. Diagnosis and management of post-transplant lymphoproliferative disease.

10.6 PALLIATIVE CARE

- i. Management of terminally ill patients

11.0 POLICIES AND PROCEDURES

The Clinical Transplant Programme shall have written policies and procedures addressing all appropriate aspects of the transplant including donor and patient evaluation, admission procedures, conditioning regimens and administration of chemotherapeutic agents, infusion of stem cells, blood products and immunosuppressive agents, GVHD prophylaxis and management, nutritional requirements as well as management of neutropaenic sepsis and transplant-related complications.

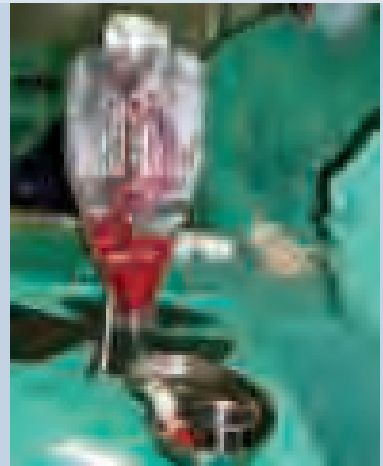
12.0 PROTOCOLS FOR CONDITIONING

- 12.1 There shall be pre-printed protocols to ensure that preparative regimens are administered safely.
- 12.2 The treatment orders shall include patient height and weight, specific dates, daily doses and route of administration of each agent.
- 12.3 The pharmacist preparing the chemotherapy shall verify the doses against the protocol or standardized regimen listed on the orders. Two persons qualified to administer chemotherapy shall verify the drug and dose in the bag and the identity of the patient before administration.

13.0 QUALITY MANAGEMENT

- 13.1 The Clinical Transplant Programme shall have a written Quality Management Plan that includes incident reporting of errors, accidents, significant outcome parameters and adverse reactions.
- 13.2 Regular meetings shall be held for review, documentation, corrective actions and reporting.
- 13.3 Transplant centres are required to submit data to the Malaysian Transplant Registry and encouraged to participate in international registries.

Appendix 1



PROPOSED CLASSIFICATION OF TRANSPLANT INDICATIONS IN ADULTS

DISEASE	STATUS	ALLOGENIC SIBLING	ALLOGENIC UNRELATED	AUTOLOGOUS
AML	CR1 low risk	CO	NR	CO
	CR1 int risk	S	CO	S
	CR1 high risk	S	CO	S
	CR2	S	S	S
	Refractory	CO	CO	NR
APML	CR1, molecular +ve	S	CO	NR
	CR2, molecular -ve	S	CO	S
ALL	CR1 low risk	CO	NR	NR
	CR1 high risk	S	S	NR
	CR2	S	S	NR
	Refractory	CO	CO	NR
CML	CP1	S	CO	NR
	AP or CP2	S	S	NR
	BP	NR	NR	NR
Myeloproliferative disease		CO	CO	NR
MDS	IPSS low	CO	CO	NR
	IPSS int	S	CO	CO
	IPSS high	S	CO	NR
CLL		CO	CO	CO
DLBCL	CR1 high IPI	NR	NR	CO
	CR2	CO	NR	S
	Refractory	CO	CO	NR
Mantle NHL	CR1	NR	NR	S
	CR2	CO	CO	S
	Refractory	CO	CO	NR
Burkitt's NHL	CR1	CO	NR	CO
	CR2	CO	CO	S
	Refractory	CO	CO	NR

HAEMOPOIETIC STEM CELL THERAPY

Lymphoblastic NHL	CR1	CO	NR	CO
	CR2	CO	CO	S
	Refractory	CO	CO	NR
Follicular NHL	CR1	NR	NR	CO
	CR2	CO	CO	S
	Refractory	CO	CO	CO
T-NHL	CR1	CO	NR	CO
	CR2	CO	CO	S
	Refractory	CO	CO	NR
Hodgkins lymphoma	CR1	NR	NR	CO
	CR2	CO	NR	S
	Refractory	CO	CO	CO
Myeloma		CO	CO	S
Amyloidosis		CO	CO	S
Severe aplastic anaemia		S	CO	NR
PNH		CO	CO	NR
Germ cell tumours	Sensitive relapse	NR	NR	S
	Refractory	NR	NR	CO
Ovarian cancer		NR	NR	D
Small cell lung Ca		NR	NR	D
Renal cell Ca	metastatic	D	NR	NR
Immune cytopaenias		D	NR	CO
SLE		D	NR	CO
Rheumatoid arthritis		NR	NR	CO
Systemic sclerosis		D	NR	CO
Multiple sclerosis		D	NR	CO
Crohn's disease		NR	NR	CO
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)		NR	NR	D
Tissue repair/angiogenesis		NR	NR	D

- S - indicated and considered as standard of care in the suitable candidate with access to facilities
 - CO - clinical option, discussion between the attending physician, patient and an independent physician* with careful consideration of the benefits versus risks is recommended
 - NR - not recommended
 - D - developmental, shall be conducted in well-designed clinical trials with ethics review and approval
- *clinician with experience in the related clinical condition

(Modified from Accreditation Subcommittee
of EBMT Recommendations, 2006)

Appendix 2



PROPOSED CLASSIFICATION OF TRANSPLANT INDICATIONS IN CHILDREN

DISEASE	STATUS	ALLOGENIC SIBLING	ALLOGENIC UNRELATED	AUTOLOGOUS
AML	CR1 low risk	NR	NR	NR
	CR1 high risk	S	CO	S
	CR2 beyond	S	S	S
ALL	CR1 low risk	NR	NR	NR
	CR1 high risk	S	CO	NR
	CR2 beyond	S	S	NR
CML	CP	S	CO	NR
	Advanced phase	S	S	NR
JMML		S	CO	NR
NHL	CR1 low risk	NR	NR	NR
	CR1 high risk	CO	NR	CO
	CR2	CO	NR	S
Hodgkin's lymphoma	CR1	NR	NR	NR
	CR2	CO	NR	S
MDS		S	S	NR
Primary immunodeficiencies		S	S	NA
Thalassaemia		S	CO	NA
Sickle cell dis		S	CO	NA
Aplastic anaemia		S	S	NA
Fanconi anaemia		S	S	NA
Blackfan- diamond anaemia		S	CO	NA
MPS-1 H Hurler		S	S	NA
MPS-1 H Hurler Scheie		NR	NR	NA
MPS-VI Maroteaux-Lamy		CO	CO	NA

Osteopetrosis		S	S	NA
Inborn Errors of Metabolism(IEM)		CO	CO	NA
Autoimmune dis		NR	NR	CO
Germ cell tumour		NR	NR	CO
Ewing's sarcoma high risk		D	NR	S
Soft tissue sarcoma		D	D	CO
Neuroblastoma high risk		CO	NR	S
Wilms tumour		NR	NR	CO
Osteogenic sarcoma		NR	NR	D
Brain tumours		NR	NR	CO
Haemophagocytic lymphohistiocytosis		S	CO	NA

S - indicated and considered as standard of care in the suitable candidate with access to facilities

CO - clinical option, discussion between the attending physician, patient and an independent physician* with careful consideration of the benefits versus risks is recommended

NR - not recommended

D - developmental, shall be conducted in well-designed clinical trials with ethics review and approval

*clinician with experience in the related clinical condition

(Modified from Accreditation Subcommittee
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Appendix 3



REFERENCE

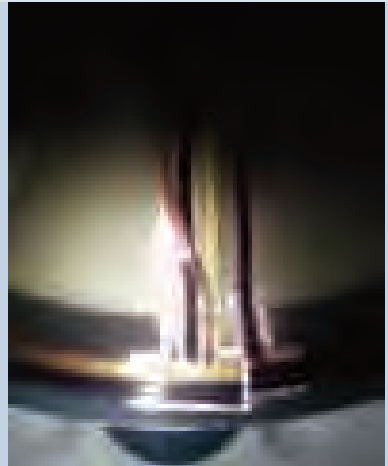
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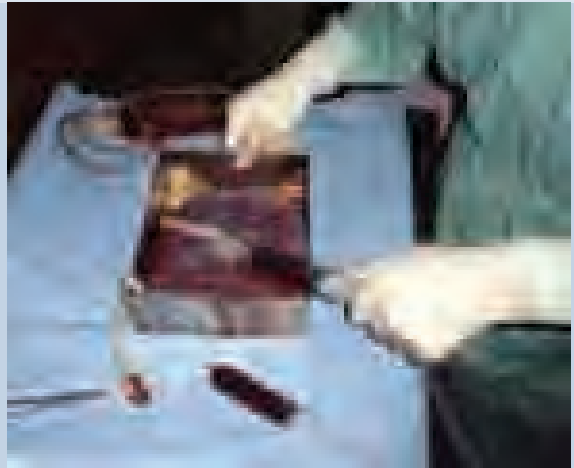
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